



SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT PTO-1449	ATTY. DOCKET NO. 10793/52	SERIAL NO. 10/058,066
	APPLICANT BARTON et al.	
	FILING DATE January 29, 2002	GROUP 1617

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE
A	5,872,147	February 16, 1999	Bowen			
	6,576,659	June 10, 2003	Fishbein			
	6,670,351	December 30, 2003	Berger			
	10/799,197	March 12, 2004	Fishbein			
	10/799,264	March 12, 2004	Fishbein			
	2003/0049716	March 13, 2003	Barton et al.			
	2002/0091155	July 11, 2002	Berger			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
A		Arora et al., "Respiratory Muscle Strength and Maximal Voluntary Ventilation in Undernourished Patients," Am Rev Respir Dis., Vol. 126, pp.5-8 (1982)
		Aulick et al., "Increased Peripheral Amino Acid Release Following Burn Injury" Surgery, Vol. 85, pp. 560-565 (May 1979)
		Bessey et al., "Post Traumatic Skeletal Muscle Proteolysis: The Role of the Hormonal Environment," World J. Surg., Vol. 13, pp. 465-470 (1989)
		Bistrian, "Protein Status of General Surgical Patients" JAMA, Vol. 230, pp. 858-860 (November 1974)
		Chandra, "Nutrition, Immunity, and Infection: Present Knowledge and Future Directions," Lancet, pp. 688-691 (March 1983)
		Chicago Tribune (September 20 1991)North Sports Final Edition Business Section page 1
		Daly, "Malnutrition," in American College of Surgeons Scientific American Surgery, Scientific American, Inc. New York, pp. 21-1-12-18 (1991)
		DeBiasse et al., "What is Optimal Nutritional Support?", New Horizons, Vol., 2 No. 2, pp. 122-130 (May 1994)
		Demling and DeSanti, "Oxandrolone, an Anabolic Steroid Significantly Increases the Rate of weight Gain In the Recovery Phase After Major Burns," J. Trauma, Vol. 43, No. 1., pp. 47-51 (1997)
		Demling et al., "Micronutrients in Critical Illness," Crit Care Clin North Am., Vol. 11, No. 3 pp. 651-673 (July 1995)

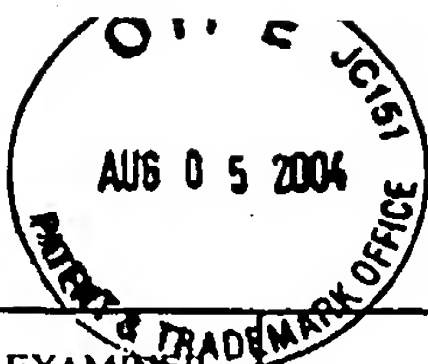


EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
J	Demling et al., "The Rate of Restoration of Body Weight After Burn Injury, Using the Anabolic Agent Oxandrolone, is not Age Dependent," Burns, Vol. 17, pp. 46-51 (2001)
	Demling, "Oxandrolone, an Anabolic Steroid; Enhances the Healing of a Cutaneous Wound in the Rat," Wound Repair Regen., Vol. 8, No. 2, pp. 97-102 (March - April 2000)
	Demling and DeSanti, "Closure of the Non-Healing Wound Corresponds with Correction of Weight Loss Using the Anabolic Agent Oxandrolone," Ostomy/Wound Management, Vol. 44, No. 10, pp. 58-68 (October 1998)
	Demling et al. "The Anabolic Steroid, Oxandrolone, Reverses the Wound Healing Impairment in Corticosteroid-Dependent Burn and Wound Patients," Wounds, Vol. 13, No. 5, pp. 203-207 (September/October 2001)
	Demling, "Comparison of the Anabolic Effects and Complications of Human Growth Hormone and the Testosterone Analog, Oxandrolone, After Severe Burn Injury," Burns, Vol. 25, pp. 215-221 (1999)
	DeSanti et al., "Development of a Burn Rehabilitation Unit: Impact on Burn Center Length of Stay and Functional Outcome," Journal of burn Care & Rehabilitation, Vol. 19, No. 5, pp. 414-419 (1998)
	Ehrlich and Hunt "The Effects of Cortisone and Anabolic Steroids on the Tensile Strength of Healing wounds" Ann Surg., Vol. 170, No. 2, pp. 203-206 (August 1969)
	Eisenberg "Effects of Androgens, Estrogens and Corticoids on Strontium Kinetics in Man," J. Clin. Endocr., Vol. 26, pp. 566-572 (May 1996)
	Eisenberg 65 Chemical Abstracts: 40387 (1996)
	Evans et al., "Protein Metabolism and Endurance Exercise," Phys Sport Med, Vol. 11, pp. 63-67, 71-72 (1983)
	Ferraresi, "Clinical Profile of Oxandrin" BTG Pharmaceuticals (April 1996)
	Frontera et al., "Strength Conditioning in Older Men: Skeletal Muscle Hypertrophy and Improved Function," J Appl. Physiol, Vol. 64, No. 3, pp. 1038-1044 (1988)
	Furst et al., "Evidence for a Nutritional Need for Glutamine in Catabolic Patients", Kidney Int Suppl. Vol. 27, pp. 287-292 (November 1989)
	Gatzen, et al., "Growth Hormone Attenuates the Abnormal Distribution of Body Water in Critically Ill Surgical Patients," Surgery, Vol. 112, pp. 181-187 (1992)
	Gontzea, "the Influence of Muscular Activity on Nitrogen Balance and on the Need of Man of Proteins," Nutr Rep. Int. Vol. 10, pp. 35-43 (July 1974)
	Grant, "Patient Selection" in Handbook of Total Parenteral Nutrition, Saunders, pp. 7-46 (1980)
	Hausmann et al., "Anabolic Steroids in Polytrauma Patients, Influence on Renal Nitrogen and Amino Acid Losses: A Double Blind Study," J. Parent. Enteral, Nutr., Vol. 14 No. 2, pp. 111-114
J	Helfman and Falanga, "Stanozolol as a Novel Therapeutic Agent in Dermatology" J. of the American Acad. Of Dermatology, Vol. 33, No. 2, pp. 254-258 (August 1995)
	Herndon et al., "Effect of Propranolol Administration on Hemodynamic and Metabolic Response of Burned Pediatric Patients," Ann Surg. Vol. 208, pp. 484-492 (October 1988)
	Herndon, et al., "Effect of Recombinant Human Growth Hormone on Donor Site Healing in Severely Burned Children" Ann Surg. Vol. 212, pp. 424-431 (October 1988)
	Hickson et al., "Glutamine Prevents Down-Regulation of Myosin Heavy Chain Synthesis and Muscle Atrophy for Glucocorticoids," Am J Physiol, Vol. 268, pp. 730-734 (1995)
	Jahoor et al., "Dynamics of the Protein Metabolic Response to Burn Injury," Metabolism, Vol. 37, No. 4, pp. 330-337 (1988)
	Jeevanadam et al., "Decreased Growth Hormone Levels in the Catabolic Phase of Severe Injury," Surgery, Vol. 111, pp. 495-502 (May 1992)
	Jekot and Prudy, "Treating HIV/AIDS Patients with Anabolic Steroids" AIDS Patients Care, pp. 68-74 (April 1993)
	Karim et al., "Oxandrolone Disposition and Metabolism in Man" Clin. Pharmacol Ther., Vol. 14, pp. 862-869 (1973)
	Keys et al., the Biology of Human Starvation, University of Minnesota Press, Minneapolis, (1950)
	Knox et al., "Increased Survival After Major Thermal Injury: The Effect of Growth Hormone Therapy in Adults," J. Trauma, Vol. 39, No. 3, pp. 526-532 (1995)
	Kochler et al., "Achieving Healing of Non-Healing Pressure Ulcers," 1998 WOCN 30 th Annual Conference, p. 37 (1998)
J	Lacey et al., "Is Glutamine a Conditionally Essential Amino Acid?" Nut rev. Vol. 48, NO. 8, pp. 297-309 (1987)

9/30/04



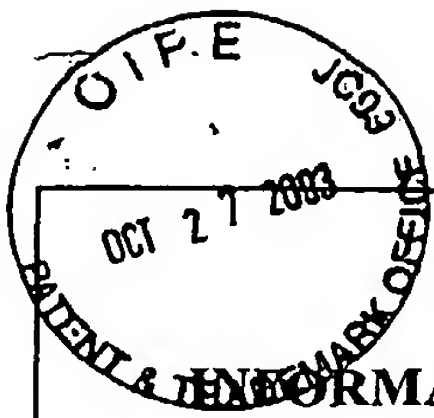
PATENT EXAMINER'S OFFICE INITIALS		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
✓		Lemon, "Protein and Exercise Updated 1987," Medicine and Science in Sports and Exercise, Vol. 19, pp. 179-190 (1987)
		Levien et al., "Reviews of Trimetrexate and Oxandrolone," Hospital Pharmacy, Vol. 29, No. 7, pp. 696-702, 705-708 (July 1994)
		Martindale, The Extra Pharmacopoeia 28 th edition, The Pharmaceutical Press, London, Reynolds and Prased Eds., p. 1430 (1982)
		Mendenhall et al., "A Study of Oral Nutritional Support with Oxandrolone in Malnourished Patients with Alcoholic Hepatitis: Results of a Department of Veteran Affairs Cooperative Study" Hepatology, Vol. 17, No. 4, pp. 564-576 (1993)
		Mendenhall et al., "Short -Term and Long-Term Survival in Patients with Alcoholic Hepatitis Treated with Oxandrolone and Prenisolone," N. Engl.J.Med, Vol. 311; pp. 1464-1470 (December 6, 1984)
		Meredith et al., "Dietary Protein Requirements and Protein Metabolism in Endurance-trained Men," J. Appl. Physiol, Vol. 66, No. 6, pp. 2850-2856 (1987)
		Moore "Response to Starvation and Stress," Metabolic Care of the Surgical Patient, pp. 202-275 (1959)
		Newsome et al., "Weight Loss Following Thermal Injury," Ann Surg. Vol. 178, pp. 215-217 (August 1973)
		PDR 38 Edition 1984 Physicians' Desk References pp. 1840-1841
		PDR 42 Edition 1988 Physicians' Desk References pp. 1975-1976
		PR Newswire, 0828P8715, "Gynex Obtains International Rights to Drug to Treat For Growth Disorders, AIDS" (August 28, 1991)
		Reichsman et al., "Muscle Protein Changes Following Eccentric Exercise in Humans," Eur. J. Appl. Physiol., Vol. 62, No. 4, pp. 245-250 (1991)
		Roberts et al., "Dietary Bioactive Peptides," in New Horizons: Frontiers in Critical Nutrition, Society of Critical Care, Fullerton, California, Vol. 2, No. 2, pp. 237-243 (May 1994)
		Schwartz and Miller, "Androgens and Anabolic Steroids," in Modern Pharmacology, Second Edition, Little Brown and Company, Boston/Toronto, Craid and Stitzel Eds., pp. 905-924 (1986)
		Sherman et al., "Growth Hormone Enhances Reepithelialization of Human Split-Thickness Skin Graft Donor Sites" Surg Forum, Vol. 40, pp. 37-39 (1989)
		Souba et al., "oral Glutamine Reduces Bacterial Translocation Following Abdominal Radiation," Surg. Res., Vol. 48 No. 1, pp. 1-5 (January 1990)
		Stehle et al., "Effect of Parenteral Glutamine Peptide Supplements on Muscle Glutamine Loss in Nitrogen Balance After Major Surgery," Lancet. Vol. 1, pp. 231-233 (February 1989)
		Studely "Percentage of Weight Loss: A Basic Indication of Surgical Risk in Patients with Chronic Peptic Ulcers," JAMA, Vol. 106, pp. 458-460 (February 1936)
		Tennenbaum and Shklar, "The Effect of an Anabolic Steroid on the Healing of Experimental Extraction Wounds," Oral Surg., Vol. 30, No. 6, pp. 824-834 (December 1970)
		Udupa and Chansouria, "Studies on Wound Healing," Indian S. Med. Res., Vol. 57, pp. 434-456 (March 1969)
		Walters et al., "Both Inflammatory and Endocrine Mediators Stimulated Host Response to Sepsis," Arch Surg. Vol. 121, pp. 179-190 (February 1986)
		Welbourne, "Increased Plasma Bicarbonate and Growth Hormone After an Oral Glutamine Load," Am. J. Clin. Nutr. pp. 1058-1061 (May 1995)
		Wernerman et al., "Glutamine and Ornithine-Alpha-Ketoglutarate but not Branched-Chain Amino Acids Reduce the Loss of Muscle Glutamine After Surgical Trauma," Metabolism, Vol. 38, pp. 63-66 (1989)
		Wilmore "Feeding the Patient," in The Metabolic Management of the Critically Ill, Plenum Medical Books Co., New York, Wilmore Ed. pp. 171-233 (1990)
		Wilmore et al., "Catecholamines: Mediator of the Hypermetabolic Response to Thermal Injury," Ann Surg.Vol. 180, pp. 653-669 (October 1974)
		Wilmore et al., "Influence of the Burn Wound on Local and Systemic Responses to Injury," Ann Surg., Vol. 186, No. 4, pp. 444-458 (1997)
		Wilmore et al., "Metabolic Changes in Burned Patients," Surg. Clin. North. Am., Vol. 58, No. 6. Pp. 1173-1187 (December 1978)



EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
✓		Wilmore et al., "Anabolic Effects of Human Growth Hormone and High Calorie Feedings Following thermal Injury," Surg. Gynecol Obstet. Vol. 138, pp. 875-884 (June 1974)
↓		Ziegler, "Growth Hormone Administration During Nutritional Support: What is to be Gained?", in New Horizons: Frontiers in Critical Care, Society of Critical Care, Fullerton, California, Vol. 2, No. 2, pp. 244-256 (May 1994)
✓		Ziegler et al., "Clinical Metabolic Efficacy of Glutamine-Supplemented Parenteral Nutrition After Bone Marrow Transplantation, Ann. Intern. Med. Vol. 116, pp. 821-828 (1992)

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



INFORMATION DISCLOSURE
STATEMENT
BY APPLICANT PTO-1449

ATTY. DOCKET NO.
10793/52

SERIAL NO.
10/058,066

APPLICANT
BARTON, et al.

FILING DATE
January 29, 2002

GROUP
1694

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE

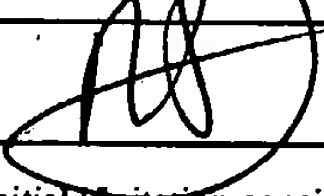
FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.	
D	Bailey et al., "Changes in the nature of the collagen during development and resorption of granulation tissue", <i>Biochem. Biophys. Acta.</i> , (1973) 328:383-390	
	Carson-Jurica, "Steroid receptor family; structure and functions", <i>Endocrine Rev.</i> , (1990) 11:201-220	
	Demling RH., et al., "Oxandrolone, an anabolic steroid, significantly increases the rate of weight gain in the recovery phase after major burns" <i>J. Trauma</i> (1997) Jul. 43:1 47-51	
	Demling RH., "Oxandrolone, an anabolic steroid, enhances the healing of a cutaneous wound in the rat", <i>Wound Repair Regen.</i> , (2000) Mar-Apr 8:2 97-102	
	Eckes et al., "Downregulation of collagen synthesis in fibroblasts within three-dimensional collagen lattices involves transcriptional and posttranscriptional mechanisms," <i>FEBS Lett.</i> , (1993), 318:129-133	
	Ehrlich HP. et al., "The effects of cortisone and anabolic steroids on the tensile strength of healing wounds", <i>Ann. Surg.</i> (1969) Aug 170:2 203-206	
	Falabella AF., American Academy of Dermatology 1998 Awards for Young Investigators in Dermatology. "The anabolic steroid stanozolol upregulates collagen synthesis through the action of transforming growth factor beta-1," <i>J. Am. Acad. Dermatol.</i> , (1998) Aug 39:2 Pt1 272-273	
	Fox M. et al., "Oxandrolone, a potent anabolic steroid", <i>J. Clin. Endocrinol.</i> (1962) 22:921-924	
	Greco RM. et al., "Differences in cell division and thymidine incorporation with rat and primate fibroblasts in collagen lattices", <i>Tissue Cell.</i> , (1992) 24:6 843-851	
	Hausmann D., et al., "Anabolic steroids in polytrauma patients: influence on renal nitrogen and amino acid losses; a double blind study", <i>J. Parent. Enteral. Nutr.</i> , (1990) 14:111-114	
	Haupt HA., et al., "Anabolic steroids: a review of the literature", <i>Am. J. Sports Med.</i> , (1984) Nov-Dec 12:6 469-484	
	Kowalewski, "Effect of anabolic steroid upon various fractions of tissue hydroxyproline in cortisone treated rats", <i>Acta Endocrinol.</i> , (1966) 53:73-78	
	Layman et al., "The nature of the collagen synthesized by cultured human fibroblasts", <i>Proc. Nat. Acad. Sci. USA</i> , (1971), 68:454-458	
	Liang et al., "Immunochemical localization of androgen receptors in human skin using monoclonal antibodies", <i>J. Invest. Dermatol.</i> , (1993), 100:663-666	

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
△		Michelsen et al., "Effect of anabolic steroid on nitrogen balance and amino acid patterns after <u>total</u> hip replacement", <i>J. Trauma</i> , (1982), May 22:5 410-413
↓		Nair et al., "Effect of anabolic steroid on experimental wound healing in calves" <i>Indian J. Ver. Surg.</i> , (1997), 18:15-16
↓		Pitkow H.S. et al., "The effects of anabolic steroid on wound healing in lower extremely skeletal muscles of normal and diabetic rats", <i>Med. Sci. Res.</i> , (1988), 16:993-997
↓		Ruizveld de Winter et al., "Androgen receptor expression on human tissue: an immunochemistry study", <i>J. Histochem. Cytochem.</i> , (1991), 39:927-936
↓		Sheffield-Moore et al., "The effect of short-term oxandrolone treatment on peripheral amino acid metabolism", <i>J. Burn Care Rehab</i> , (2000), 1:199-205
↓		Tennenbaum, "Effect of anabolic steroid on the healing of experimental extraction wounds", <i>Oral Med. Oral Path</i> , (1970), 30:824-834
↓		Vilijanto et al., "Effect of an anabolic steroid on the tensile strength of granulation tissue in various nutritional states", <i>Acta Endocrino</i> , (1962), 141:395-399
↓		Strawford et al., "Resistance exercise and supraphysiologic androgen therapy in eugonadal men with HIV-related weight loss: A randomized controlled trial", <i>JAMA</i> , (1999), 281:14 1282-1290
↓		Udupa et al., "Studies on wound healing - 3. Effect of ascorbic and acid and methionine in wound healing", <i>Indian J. Med. Res.</i> , (1969) 57:3 449-456
↓		Da Lio AL et al., "Oxandrolone ameliorates the adverse effects of corticosteroids in wound healing," <i>Surgical Forum</i> , (1999) 628-630
↓		Demling RH., "Comparison of the anabolic effects and complications of human growth hormone and the testosterone analog, oxandrolone, after severe burn injury," <i>Burns</i> , (1999) May 25:215-221
		Remington, <i>The Science and Practice of Pharmacy</i>, Alfonso R. Gennaro (Ed.) Lippincott, Williams & Wilkins (pub).
✓		Schulz et al., "A 10-Year experience with toxic epidermal necrolysis", <i>Journal of Burn Care and Rehabilitation</i> , Vol. 21, No. 3, May/June 2000, 199-204

EXAMINER		DATE CONSIDERED 9/30/04
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		